and administration of the programs of the Commission in the States of Arkansas, Colorado, Iowa, Kansas, Louisiana, Missouri, Nebraska, New Mexico, Oklahoma, and Texas.

PART 145—[AMENDED]

3. In § 145.6, paragraph (a) is revised to read as follows:

§145.6 Commission Offices To Contact for Assistance; Registration Records Available at Chicago Regional Office.

(a) Whenever this Part 145 directs that a request be directed to the FOI, Privacy and Sunshine Acts compliance staff at the principal office of the Commission in Washington, D.C., it shall be addressed or otherwise directed to the FOI, Privacy and Sunshine Acts compliance staff, Office of the Secretariat, Commodity Futures Trading Commission, 2033 K Street, NW., Washington, D.C. 20581. The telephone number of the compliance staff is (202) 254–6314. Whenever this Part 145 permits an inquiry or request to be directed to a regional office of the Commission (see §§ 145.2, 145.6(b) (Chicago regional office only) and 145.7 (a), (b) and (c)), it may be directed to the FOI, Privacy and Sunshine Acts compliance staff for direct response or referral or to the appropriate regional office (or Minneapolis sub-office) of the Commission at the following locations and telephone numbers:

Division of Economics and Education, Commodity Futures Trading Commission, One World Trade Center, Suite 4747, New York, New York 10048, Telephone: (212) 466–2071.

Division of Trading and Markets, Commodity Futures Trading Commission, Sears Tower, Suite 4600, 233 South Wacker Drive, Chicago, Illinois 60606, Telephone: (312) 353–9499.

Division of Trading and Markets, Commodity Futures Trading Commission, 510 Grain Exchange Building, Minneapolis, Minnesota 55415, Telephone: (612) 725–2025.

Division of Trading and Markets, Commodity Futures Trading Commission, 4901 Main Street, Suite 400, Kansas City, Missouri 64112, Telephone: (816) 374–2994.

Division of Enforcement, Commodity Futures Trading Commission, 10850 Wilshire Boulevard, Suite 510, Los Angeles, California 90024, Telephone: (213) 209–6783.

* * * * *

The foregoing rules shall be effective immediately. The Commission finds that the amendments relate solely to agency organization, practice and procedure and that the public procedures and publication prior to the effective date of the amendments, in accordance with the Administrative Procedure Act, as codified, 5 U.S.C. 553, are not required.

Issued in Washington, D.C. this 18th day of January, 1983.

Jane K. Stuckey,

Secretary of the Commission.

[FR Doc. 83-1589 Filed 1-20-83; 8:45 am]

BILLING CODE 6351-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 102

[Docket No. 80N-0140]

Common or Usual Name for Nonstandardized Foods; Diluted Fruit or Vegetable Juice Beverages; Extension of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule; extension of effective date.

SUMMARY: The Food and Drug Administration (FDA) is extending the period of time for compliance with the labeling requirements of the common or usual name for diluted fruit or vegetable beverages regulation for all affected products initially introduced or initially delivered for introduction into interstate commerce from July 1, 1982 to July 1, 1984.

EFFECTIVE DATE: July 1, 1984, for all affected products initially introduced or initially delivered for introduction into interstate commerce.

FOR FURTHER INFORMATION CONTACT: Elizabeth J. Campbell, Bureau of Foods (HFF–312), Food and Drug Administration, 200 C St. SW., Washington, DC 20204; 202–245–3092.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 10, 1980 (45 FR 39247), FDA published a final regulation concerning label statements for diluted fruit or vegetable juice beverages (21 CFR 102.33). The effective date was deferred until July 1, 1982, by a document published in the **Federal Register** of December 5, 1980 (45 FR 80497). Subsequently, FDA published a proposal in the **Federal Register** of March 26, 1982 (47 FR 13003) to extend the effective date to July 1, 1984, for compliance with the labeling requirements of the common or usual name for diluted fruit or vegetable juice beverages regulation.

As required by the Regulatory Flexibility Act, Executive Order 12291, and the Paperwork Reduction Act of 1980, FDA is currently reviewing the regulations concerning diluted orange juice beverages (21 CFR 102.32) and noncarbonated beverage products containing no fruit or vegetable juice (21 CFR 102.30). Because of the similarity of §§ 102.30, 102.32, and 102.33, FDA has concluded that it would be appropriate to review them together. Consequently, to avoid substantial compliance cost that may be found unnecessary should the review process result in a decision to revoke or modify the regulation, FDA published the 1982 proposal to extend the effective date to allow sufficient time for this review.

Comments in response to the proposal were received from growers and processors of cranberry products, juice trade associations, juice processors (other than cranberry juice), a State government, and one consumer. The majority of the comments received were from the cranberry growers and processors favoring the granting of the extension to allow a review of the applicability of the final regulation to high acid juice products. These comments stated that since a review of all regulations is required by the Regulatory Flexibility Act, Executive Order 12291, and the Paperwork Reduction Act of 1980, the review of this diluted juice regulation would be more cost effective if it were conducted before the regulation became effective and labels had been modified.

The agency agrees and therefore is scheduling the review of this regulation to be accomplished within the extension period.

The other comments, submitted by a State government, one consumer, a trade association, and three manufacturers, expressed concern that extending the effective date of the regulation would be a dissservice to the manufacturers who had, in good faith, relabeled their products to meet the effective date. A State official stated that the continued extension of the effective date for this regulation undermines the efforts made by State and local food regulatory agencies to encourage industry compliance with new and existing regulations.

It is true that many of the manufacturers in the diluted juice industry have already brought their labels into compliance with the labeling regulations for diluted juice beverages. It is also true that primarily the high acid juice industry is concerned about revising their labeling before the required review of the regulation is complete. FDA is not unsympathetic to the positions in which each segment of the industry finds itself. Therefore, in light of the ongoing retrospective review, the agency believes that it has articulated in this document the most resonable course to follow: the granting

of the extension. In response to the comments of manufacturers who have relabeled their products, the agency feels that the public interest is served by the relabeling because the regulations were structured to aid the consumer. However, to force all manufacturers to comply with the regulation would create an unworkable conflict: The agency would have to actively promote a position while at the same time critically and objectively reevaluating it. The agency's conclusion to grant the extension is strengthened by the fact that the manufacturers who are currently in compliance with the regulations have submitted no evidence that being in compliance with the regulation places their products at a market disadvantage or results in consumer deception. Similarly, the State comment was not supported by any specific details, without which the agency cannot fully respond, much less alter its views of the propriety of this action.

List of Subjects in 21 CFR Part 102

Common or usual name, Food labeling.

PART 102—COMMON OR USUAL NAME FOR NONSTANDARDIZED FOOD

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(n), 403, 701(a), 52 Stat. 1041 as amended, 1047–1048 as amended, 1055 (21 U.S.C. 321(n), 343, 371(a))) and under 21 CFR 5.11 as revised (see 47 FR 16010; April 14, 1982), the effective date for compliance with the labeling requirements of the common or usual name for diluted fruit or vegetable juice beverages regulation (21 CFR 102.33) is extended from July 1, 1982, to July 1, 1984, as follows: All affected diluted fruit or vegetable juice beverages initially introduced or initially delivered for introduction into interstate commerce after July 1, 1984, shall comply with 21 CFR 102.33 (45 FR 39247; June 10, 1980).

(Secs. 201(n), 403, 701(a), 52 Stat. 1041 as amended, 1047–1048 as amended, 1055 (21 U.S.C. 321(n), 343, 371(a))

Dated: January 4, 1983.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

Richard S. Schweiker,

Secretary of Health and Human Services.

[FR Doc. 83-1650 Filed 1-20-83; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 133

[Docket No. 77N-0331]

Nine Natural Cheeses; Revision Based on International Standards of Identity

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the "Definitions" section for all standardized cheeses and related cheese products, establishing a new "Methods of Analysis" section for all standardized cheeses and related cheese products, and revising and updating the standards of identity for nine cheeses and appropriate cross-referenced standards to bring the nine cheese standards into closer conformance with the recommended international Codex standards for these cheeses, thereby facilitating international trade.

DATES: Effective July 1, 1985, for all affected products initially introduced or initially delivered for introduction into interstate commerce on or after this date; voluntary compliance beginning March 22, 1983; objections by February 22, 1983. The incorporation by reference is effective March 22, 1983.

ADDRESS: Written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Eugene T. McGarrahan, Bureau of Foods (HFF–215), Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204, 202–245–1155.

SUPPLEMENTARY INFORMATION: A proposal was published in the **Federal Register** of September 19, 1978 (43 FR 42127), to revise the standards of identity for blue cheese (21 CFR 133.106), cheddar cheese (21 CFR 133.113), edam cheese (21 CFR 133.138), gouda cheese (21 CFR 133.142), gruyere cheese (21 CFR 133.149), limburger cheese (21 CFR 133.152), provolone cheese (21 CFR 133.181), samsoe cheese (21 CFR 133.185), swiss and emmentaler cheese (21 CFR 133.195), and, by cross-reference, cheddar cheese for manufacturing (21 CFR 133.114), low sodium cheddar cheese (21 CFR 133.116), and swiss cheese for manufacturing (21 CFR 133.196).

The purpose of the proposed revisions was to: (1) Provide for full ingredient declaration; (2) relax recipe requirements to permit the use of safe and suitable ingredients that do not change the basic identity of the food or adversely affect the physical or chemical characteristics; and (3) amend compositional requirements to be consistent with the "recommended international Codex standards" (Codex standards), where such consistency will promote honesty and fair dealing in the interest of consumers. The proposal would also amend the "Definitions" section and establish a new "Methods of Analysis" section.

A notice published in the **Federal Register** of December 19, 1978 (43 FR 59053) extended the comment period to March 19, 1979.

Twenty-six letters, each containing one or more comments, were received in response to the September 19, 1978, proposal. The issues raised in the comments and FDA's responses are as follows:

Definitions

1. One comment requested that the phrase "the milk may be clarified and may be adjusted by separating part of the fat therefrom" be added to the proposed definition of milk in § 133.3(a) (21 CFR 133.3(a)).

FDA agrees and the definition for "milk" is changed accordingly.

2. One comment requested that "dehydrated cream" be added to the list of products included in the definition for "cream" in § 133.3(c).

FDA advises that this addition is unnecessary because it considers dry and dehydrated to be the same, and dry cream is already provided for in the definition for cream.

3. One comment requested that a definition for "milkfat", which would include all the products in the proposed definition for cream as well as products like anhydrous milkfat, butter, and butteroil, be added to § 133.3 and that each of the standards provide for the use of milkfat as an optional dairy ingredient. The comment asserted that these products are all commonly known as milkfat and that by defining them as such they could be declared as "milkfat" in the ingredient statement.

FDA does not agree that butter, butteroil, and anhydrous milkfat are commonly known as milkfat. While milkfat is the starting material for all three ingredients, changes in the physical characteristics of milkfat occur during the manufacturing procedures (i.e., from a fat-in-water emulsion to a water-in-fat emulsion) which make these ingredients immiscible with the milk and other dairy ingredients that are combined to make cheese. Further, butter, butteroil, and anhydrous milkfat are not provided for in the standards of identity for cheeses and related cheese products and no petition has been

submitted to the agency to include such products in a definition of milkfat and amend each of the standards in 21 CFR Part 133 to provide for the use of "milkfat" as an optional dairy ingredient. Under these circumstances, to concur with the comment would have the effect of authorizing the use of ingredients which have not been shown to be suitable for the desired use. In addition, FDA points out that a definition of "milkfat" to facilitate declaration of listed ingredients as "milkfat" is unnecessary because the ingredient labeling provisions in the final regulations set forth below already state that the dairy ingredients may be declared, in descending order of predominance, by the terms "milkfat and nonfat milk" or "nonfat milk and milkfat" as appropriate. FDA, therefore, concludes that the changes requested by this comment are inappropriate and is not so providing in the regulations.

4. One comment requested that a definition for "microbial cultures" be included in § 133.3. This would permit label declaration of flavor- and acid-producing microbial cultures as "cultures" in the ingredient statement.

A definition of "microbial cultures" is not necessary. The current labeling regulations (21 CFR Part 101) permit bacterial cultures to be declared in the ingredient statement by use of the word "cultured" followed by the name of the substrate (e.g., "cultured milkfat and nonfat milk"). This method of declaring the use of bacterial cultures is consistent with the provisions of other cheese standards of identity. Furthermore, FDA is currently considering a petition to amend Part 101 to permit the term "cheese cultures" to be used on the label to encompass all of the types of microbial cultures (bacterium, yeast, mold) that might be used in the manufacture of cheese. Therfore, FDA s not establishing a definition for "microbial cultures" in § 133.3.

Methods of Analysis

5. One comment requested that a method of determining the milkfat content in the solids, or fat on a dry basis, be added to the proposed "Methods of Analysis" section (§ 133.5). The comment expressed the opinion that the traditional fat on a dry basis method is a better enforcement tool which will prevent manipulation of the product and which will afford greater protection to the consumer as well as greater stability to the industry. The comment suggested that the method for calculating milkfat content from dry matter, now in the current cheddar cheese standard (§ 133.113(c)), be added to the proposed "Methods of Analysis" section as § 133.5(d).

FDA agrees and is adding paragraph (d) to § 133.5 to provide for the requested method of calculating fat on a dry basis. FDA also advises that it is updating the "Methods of Analysis" section to reference the 13th edition of the "Official Methods of Analysis of the Association of Official Analytical Chemists" (AOAC).

General Comments Related to All the Proposed Cheese Varieties

6. One comment suggested that the concept of "safe and suitable" apply only to functional ingredients such as enzymes, stabilizers, and antimicrobial agents. The comment stated that the "Dairy ingredients should not be classified in the same category as 'safe and suitable ingredients'." The comment asserted that inclusion of dairy ingredients under "safe and suitable" will lead to economic deception by allowing use of "nonstandardized undefined 'safe and suitable' milk-derived ingredients" and that the consumer will have no assurance that the standardized product contains basic dairy ingredients.

FDA considered changing its "safe and suitable" policy to apply only to categories of optional functional ingredients that are used at levels of less than 5 percent and do not alter the basic characteristics of the food. A notice requesting public comment on a tentative proposed revision was published in the **Federal Register** of December 21, 1979 (44 FR 75990). Upon review and evaluation of the comments received in response to the tentative proposed revision, FDA has determined that, at this time, it would be in the best interest of consumers and regulated industry to retain the current policy for use of safe and suitable optional ingredients in standardized foods. Elsewhere in this issue of the **Federal Register** FDA is announcing this decision. The regulation set forth below provides for the use of "safe and suitable" ingredients consistent with this policy. In addition, FDA advises that the dairy ingredients that may be used in the cheeses included in the proposal are specifically listed in the individual standards. Milk-derived ingredients are not among the optional dairy ingredients listed and may not be used in these cheeses.

7. One comment opposed permitting the use of caseinates as safe and suitable dairy ingredients.

Caseinates were not among the dairy ingredients proposed for use nor are they provided for in the final regulation.

8. One comment requested that the provision allowing the use of lactic acid-producing bacteria naturally present in milk be retained in all the appropriate standards. The comment contended that these naturally occurring bacteria would have to be destroyed before the culture is added if the naturally occurring bacteria are not specifically permitted for use.

The proposed standards provided that the dairy ingredients used are "subjected to the action of a lactic acid-producing bacterial culture" without specifying whether the source of the culture was added to the milk or natural to the milk (see § 133.106(a)(3); proposed as § 133.106(a)(4)). Therefore, FDA does not believe that it is necessary to specifically provide for naturally occurring bacteria that are desirable to the cheese-making process and is not making the requested change in the final regulation. FDA advises that naturally occurring harmless lactic acid-producing bacteria in milk are permitted for use in these cheeses.

9. One comment pointed out that the method of declaring ingredients on the label of cheeses is deceptive because neither salt nor color need be declared. The comment stated that this situation could be remedied by requiring manufacturers to title the ingredient statement "partial list of ingredients" or "incomplete list of ingredients".

FDA does not have the authority under section 401 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 341) to require the label declaration of mandatory ingredients in standardized foods (e.g., salt in several types of cheese). Color in butter, cheese, and ice cream is exempted from label declaration by section 403(k) of the act (21 U.S.C. 343(k)) (§§ 74.1705 and 101.22 require that FD&C Yellow No. 5, when used in butter, cheese, or ice cream, be declared on the label). FDA urges manufacturers to declare, voluntarily, the presence of these exempted ingredients, when used, on the label of the cheese. FDA is not requiring that manufacturers who do not choose to declare the presence of these ingredients title the ingredient statement on their foods "partial list of ingredients" or "incomplete list of ingredients" because such a title may be confusing to consumers.

10. One comment expressed the opinion that a better method of label declaration of ingredients would be by specific ingredient rather than by general terms such as "milkfat and nonfat milk", "nonfat milk and milkfat", or "milk". This change would prevent potential consumer confusion when the

use of reconstituted or concentrated milk is declared simply as "milk".

FDA does not agree with this comment. This method of ingredient declaration is not deceptive because differences in the form of the dairy ingredients used (i.e., liquid, concentrated, or dried) have no perceptible effect on the final product.

FDA notes that dairy ingredients used in cheese may be declared as "milkfat and nonfat milk", "nonfat milk and milkfat", or in accordance with Part 101 (21 CFR Part 101) labeling regulations which, in § 101.4(b)(4), provide that milk, concentrated milk, reconstituted milk, and dry whole milk may be declared as "milk" in the ingredient statement. Therefore, the requested change is not being made in the final regulation.

11. One comment stated that FDA apparently misinterpreted the intention of the Codex standards committee in providing for multiple milkfat and moisture levels in blue, limburger, and samsoe cheeses, and in expanding this Codex concept to cheddar and swiss and emmentaler cheeses. The comment maintained that the Codex committee provided for variable milkfat levels in the former three cheeses in recognition of differing fat levels traditional for those varieties in certain member countries and to encourage those countries to accept the proposed Codex standards. The comment asserted that the intent of the Committee was that a country would adopt only the minimum milkfat and maximum moisture level combination traditional in that country. Several comments were against multiple milkfat and moisture levels in cheese standards because they work to destroy the integrity of the standards and of the cheeses. Others asserted that the cheese standards establish a definite identity, name, and minimum level of composition for these foods, which would be destroyed with the inclusion of variable milkfat and moisture levels. Several of those commenting thought that allowing cheeses of various milkfat and moisture levels to be marketed under the same name would be confusing to the consumer and would result in destruction of consumer trust in traditional products. Some comments, while recognizing the value of lower fat cheeses, suggested that lower fat types of standardized cheeses should not be identified with traditional names. It was suggested that separate standards with new names be established.

FDA advises that, while there may have been the understanding that some countries would not accept multiple composition requirements, as provided for in the recommended Codex standards, these provisions are, in fact, part of the Codex standards and were considered in accordance with 21 CFR 130.6. Because compositional variations of several cheese varieties that are covered by U.S. standards of identity were appearing in the marketplace, FDA extended the multiple composition concept to cheddar and swiss cheeses. However, FDA has been persuaded by the comments received that consumers may be confused if multiple milkfat and moisture levels are provided for in U.S. varietal cheese standards of identity under the same varietal name and that the physical attributes of a specific cheese variety could be altered. Therefore, FDA is not providing for multiple fat and moisture level requirements, but is retaining the minimum fat and maximum moisture requirement as now set forth in paragraph (a) of §§ 133.106, 133.113, 133.152, 133.185, and 133.195 of the standards of identity for blue, cheddar, limburger, samsoe, and swiss and emmentaler cheeses.

12. Most of the comments opposed, for various reasons, the declaration of the percent fat as part of the name of the cheese.

FDA is not establishing variable milkfat and moisture levels in any of the natural cheese standards. Therefore, a percent fat declaration as part of the name of the cheese is no longer necessary and is not provided for in the final regulation.

FDA advises that it is retaining the current method of expressing fat content (i.e., on a dry weight or solids basis) in §§ 133.106, 133.113, 133.138, 133.142, 133.149, 133.152, 133.181, 133.185, and 133.195. This method of expressing fat content is consistent with that in the Codex standards as well as in other U.S. standards of identity for cheeses.

13. Several comments were received in response to FDA's request for information about the use of the hydrogen peroxide/catalase treatment of milk to be used for cheese manufacturing. Two comments requested that the use of this treatment be retained in the standards of identity for cheddar cheese (§ 133.113) and swiss and emmentaler cheese (§ 133.195) because it destroys harmful bacteria without destroying beneficial enzymes. The comments asserted that the treatment also produces a more consistent flavor in the cheeses. One comment, by a large producer of cheese, stated that it regularly uses a process relying on this method of milk treatment. Another comment maintained that the hydrogen peroxide/catalase method should be retained even if it isn't widely used because it could prove to be a low-energy alternative to pasterization and of increasing value in the future.

FDA proposed to eliminate provisions for the use of the hydrogen peroxide/catalase treatment of milk from the standards for cheddar cheese and swiss and emmentaler cheese and cross-referenced standards because it was not aware that any manufacturers were using the process. In view of the fact that some manufacturers are still using this method of reducing the bacterial population of cheese milk, provisions for the use of the hydrogen peroxide/catalase treatment of milk are being retained in §§ 133.113 (a)(3) and (b)(3)(v) and 133.195 (a)(3) and (b)(3)(vi) (cheddar and swiss and emmentaler cheese, respectively).

14. One comment requested that whey proteins be permitted as optional ingredients in natural cheeses. The comment asserted that allowing the direct incorporation of such proteins would recognize the desirability of retaining as many of the nutrients of the milk source as possible in the final cheese product.

FDA is not making the requested change because whey proteins might adversely affect the physical quality of the cheese (e.g, slow rennetting, poor matting, and short texture) and because it has no information to substantiate the possible nutritional benefits arising from the use of whey proteins. FDA invites any interested person to submit a petition, with supporting data, consistent with the requirements of 21 CFR 10.30, proposing to amend specific cheese standards of identity to permit the use of whey proteins.

15. One comment requested permitting only *beta*-carotene as coloring in the proposed cheese standards because it has vitamin A activity and all the cheeses are yellow. The comment expressed the opinion that the U.S. standards are too broad because they allow the use of artificial color, whereas Codex standards allow only *beta*-carotene to be used.

FDA believes that the request is inappropriate. FDA is aware of the vitamin A activity of *beta*-carotene, but emphasizes that the purpose of permitting the use of *beta*-carotene in the standard is as a coloring agent, and not as a nutrient. Further, the comment incorrectly characterized the Codex standard. That standard permits the use of annatto, as well as *beta*-carotene, to impart a yellow color to those cheeses where a yellow color is desired. Finally, the comment is incorrect in asserting that all cheeses are yellow. Certain cheeses, such as provolone cheese and blue cheese, are made from types of

milk (animal source and season) which result in a relatively white cheese. When the cheese curd used in formulating these cheeses is made from milk relatively high in yellow pigments, as is true at certain times of the year, a blue or green color is used to mask the yellow color and thus to produce the near-white color which is characteristic of such cheeses. FDA, therefore, is not making the requested changes.

16. One comment requested that the minimum age requirement for blue (§ 133.106), gruyere (§ 133.149), and swiss and emmentaler (§ 133.195) cheeses be moved from the description paragraph to the paragraph delineating the manufacturing procedure so that manufacturers may use alternate procedures using shorter curing times with the provision that the resulting cheese is chemically and physically identical to the cheese produced by the prescribed manufacturing procedure. No data were submitted in support of this comment.

FDA is not making the requested changes because it has no data which indicate that the organoleptic and physical qualities characteristic of these cheeses can be developed using shorter curing times. FDA notes that the proposed curing times for these cheeses are the same as those now required for these three cheeses and are consistent with the Codex requirements.

17. One comment requested that proposed paragraph (b)(3)(iv) of § 133.113 (cheddar cheese), § 133.138 (edam cheese), § 133.181 (provolone cheese), § 133.185 (samsoe cheese), and § 133.195 (swiss and emmentaler cheese), proposed paragraph (b)(3)(iii) of § 133.149 (gruyere cheese) which limits use of antimycotics to the surface of cuts and slices in consumer-sized packages, and proposed paragraph (b)(3)(iv) of § 133.106 (blue cheese) which permits the use of antimycotics on the surface of the blue cheese be expended to read "Antimycotic agents, applied to the surface of the cheese." The comment also requested that the cross-referenced standards for cheddar cheese for manufacturing (§ 133.114) and swiss cheese for manufacturing (§ 133.196) permit the use of antimycotic agents. The comment maintained that this requested extension of the use of antimycotics is necessary to improve the quality of the product and protect consumers. No supporting data were submitted with the comments.

FDA concludes that it is inappropriate to make the requested changes at this time because such changes should be subject to the proposed rulemaking proceedings whereby interested persons have an opportunity to comment. FDA invites interested persons to submit a petition supported by adequate data demonstrating that extending the use of antimycotics will not lead to these cheeses being prepared, packed, or held under unsanitary conditions whereby they may become contaminated with filth or otherwise be rendered injurious to the health of the consumer. One comment, which supported restricting the use of antimycotics, pointed out that the requested extended use of antimycotics would result in companies that cut and pack cheese in consumer-sized packages incurring additional costs for either testing to determine the quantity of antimycotics already in the cheese or for trimming the whole cheese in an effort to remove antimycotics from the surface. Both of these procedures result in added costs to the company which would be passed on to consumers.

Comments Related to the Proposed Amendments to Specific Cheese Varieties

Blue Cheese

18. One comment stated that the 60-day curing period required in paragraph (a) of § 133.106 (blue cheese) is no longer technologically necessary if the cheese meets the mold development requirement specified in proposed paragraph (a)(1) (i.e., "It is characterized by the presence of bluish-green mold throughout the cheese"). The comment suggested that the 60-day holding period requirement for all blue cheese be replaced with the standard requirement that blue cheese made from unpasteurized dairy ingredients be held at not less than 35° F for a minimum of 60 days. No data were submitted in support of this comment.

FDA is not making the requested change in the final regulation because it has no data which demonstrate that the 60-day holding period requirement for blue cheese is no longer necessary to ensure that the enzymes produced by the *Penicillium roquefortii* have had an opportunity to break down fats and proteins in the curd to produce flavor components characteristic of blue cheese. The mere presence of blue-green mold is not a guarantee that these flavor components are present.

19. One comment stated that the requirement that *Penicillium roquefortii* spores be added to the curd is out of date. The standard for blue cheese would be more technically correct if proposed § 133.106(a)(4) were changed to permit the addition of spores to the dairy ingredients rather than only to the curd.

FDA concludes that this change is not necessary because the procedure described in proposed § 133.106(a)(4) may be modified as provided for in § 133.106(a)(1) which states that any other procedure may be used which produces a finished cheese having the same physical and chemical properties.

20. One comment requested that FDA continue to allow the use of vegetable fat or oil as a coating on the rind of the cheese because such coating limits the oxygen available to microorganisms that may grow on the surface, thereby having a preservative effect.

FDA agrees and is providing for the optional use of vegetable fat or oil as a coating on the rind in § 133.106(b)(3)(vi). FDA notes that the word "homogenized" was omitted from § 133.106(a)(3) of the proposal. Currently, § 133.106(b) provides for homogenization of the dairy ingredient used in the manufacture of blue cheese. Obviously the omission was inadvertent. FDA has corrected the omission by inserting the word "homogenized" in the final regulation.

Cheddar Cheese

21. One comment favored retaining the word "cheese" as an alternative name for "cheddar cheese" (§ 133.113) because the word "cheese" is erroneously used generically, and this usage could confuse or mislead consumers.

FDA does not agree with this comment. The word "cheese", as pointed out by another comment, is understood by consumers as a generic term describing a universe of cheese varieties, not as a specific reference to "cheddar cheese". Consequently, FDA believes that retention of the word "cheese" as an alternative name will create more confusion. Therefore, FDA is not retaining the word "cheese" as an alternative name for "cheddar cheese".

22. One comment requested that cultured milk, cultured nonfat milk, and cultured cream be added to the list of optional dairy ingredients that may be used in the manufacture of cheddar cheese because, technologically, they can be used to produce the same cheddar cheese produced using traditional, noncultured forms of these dairy ingredients. No data or grounds to support this change were submitted.

FDA is not convinced, nor are there data to support the contention, that cultured forms of dairy ingredients, used as basic ingredients, will produce the same cheese as produced from the traditional, noncultured dairy ingredients. FDA also has no information about whether the microorganisms used in the cultured

dairy ingredients might interfere with the microorganisms necessary to the production of the cheese. Therefore, the requested change is not being made in the final regulation.

Cheddar Cheese for Manufacturing

23. One comment requested that the proposed amendment of the standard for cheddar cheese for manufacturing (§ 133.114) be changed to require pasteurization of the diary ingredients used. The comment asserted that the lack of this requirement in the proposed standard "ignores the potential public health hazard and does not help ensure safety of the product." The comment further asserted that this requested change would be consistent with proposed amendments to the standard for skim milk cheese for manufacturing (21 CFR 133.189), published in the **Federal Register** of October 4, 1977 (42 FR 53979).

Requiring pasteurization for cheddar cheese for manufacturing is not necessary because the cheese is to be used in the manufacture of cheese products, such as pasteurized process cheese and other foods, and not for direct human consumption. The manufacturing process for these foods (e.g., pasteurized process cheese products) includes a pasteurization heat treatment that is sufficient to destroy pathogenic bacteria that may have been present in the original cheese ingredients. Therefore, FDA is not making the requested change. FDA notes that the purpose of the proposed amendments to the standard for skim milk cheese for manufacturing (reproposed Docket No. 77P-0071, November 30, 1982 (47 FR 53914)) was to provide a cheese for direct human consumption as well as for manufacturing purposes.

Low Sodium Cheddar Cheese

24. One comment pointed out that salt need not be excluded from the standard for low sodium cheddar cheese (§ 133.116) since a maximum level of sodium is set by the standard. The comment stated that even a small quantity of salt is technologically important as an aid in removing moisture from the curd and producing a more palatable product.

FDA agrees and in the final rule is deleting paragraph (a) of § 133.116 and is redesignating proposed paragraphs (b), (c), (d), and (e), of § 133.116 as (a), (b), (c), and (d), respectively.

Gouda Cheese

25. One comment asked that the proposed milkfat minimum for gouda cheese (§ 133.142) be raised to 28 percent, by weight, which is comparable to 48 percent on a dry basis, the minimum set by the Codex standard.

FDA does not believe that it is necessary to raise the minimum milkfat level of gouda cheese to 48 percent, on a dry basis, to be consistent with the Codex standard. The minimum milkfat content, on a dry basis, in the current U.S. standard for gouda cheese is 46 percent. This 46 percent minimum is not in conflict with the Codex standard because, as a minimum, it does not impede either the production of a higher fat gouda cheese in this country or the importation of a higher fat gouda cheese from another country into this country. Therefore, this requested change is not being made in the final regulation.

Provolone Cheese

26. Several comments objected to inclusion of the word "smoked", being proposed in § 133.181(c)(2)(ii), in the name of the food when provolone cheese is smoked because this term may be deceptive and potentially confusing to consumers who expect provolone cheese to have a smoked flavor. Therefore, the comments requested that the requirement for the label declaration of the term "smoked" for the smoked product be replaced with the label declaration of "not smoked" for the product that is not smoked, as in the current standard.

FDA agrees that the potential for consumer confusion exists in requiring the word "smoked" as part of the name of the food, so it is also providing for use of the term "not smoked", when appropriate. Therefore, the standard for provolone cheese has been changed accordingly in § 133.181(c)(2)(i) and (ii).

27. Several comments objected to the ingredient declaration requirement for provolone cheese because such a declaration would imply to the consumer that provolone is not a standardized cheese. The declaration would further imply that the manufacturer, rather than FDA, has control over the selection of the various ingredients that can be used to produce provolone cheese. The comments requested that the required ingredient declaration be dropped.

FDA does not agree with this comment. The ingredient declaration is required because cheese manufacturers have many choices of ingredients within specified classes of ingredients. Furthermore, consumers have expressed the desire to know what ingredients are in the foods they consume. Therefore, FDA is not making the requested change.

28. One comment wanted to retain the alternative name "pasta filata" in the provolone cheese standard because the name provides a basis for the designation of different shapes and sizes with which the consumer is familiar (e.g., "salami pasta filata").

The term "pasta filata" more correctly refers to a family of cheeses, each of which have a pasta filata (curd kneading and stretching) step in their manufacturing procedure. Examples of pasta filata-type cheeses are mozzarella, caciocavallo siciliano, and provolone. Furthermore, FDA believes that the name "provolone" is more commonly associated with shape or size designations such as "salami" or "bacchini" than is the term "pasta filata". Therefore, FDA is not retaining "pasta filata" as an alternative name for provolone cheese.

29. Several comments pointed out an apparent error in proposed § 133.181(a)(1) of the standard for provolone cheese. The last sentence of the paragraph reads "If the dairy ingredients used are not pasteurized, the cheese is cured at a temperature of 35° F for at least 60 days." The comments pointed out that the words "not less than" should precede "35° F".

FDA agrees and the final regulation is changed accordingly.

30. One comment suggested that language be added to the proposed amendment of the provolone standard that would allow the use of rope or twine to encase the cheese before drying, the addition of smoke flavor, and the use of paraffin and similar coatings. The comment maintained that the addition of this language will protect the integrity of the standard and the traditional characteristics of provolone cheese.

FDA doe not believe that either the integrity of the standard or the traditional characteristics of the cheese would be adversely affected if the suggested language is not added to the proposed standard for provolone cheese. There is no need to specifically provide for the use of rope, twine, or paraffin or other coatings. It should be noted that the standard does not prevent their usage as packaging materials. Provision for the addition of smoke flavor, which is in the current standard, was removed from the proposed standard because the smoke-flavored cheese is covered by the standard of identity for spiced, flavored standardized cheeses (§ 133.193). Therefore, the requested language is not being added to the standard for provolone cheese.

31. Several comments objected to listing "clotting enzymes" and "milk" as optional ingredients in the proposed amendment of the standard for

provolone cheese. The comments said that some form of milk is absolutely essential to cheese production and that clotting enzymes are intrinsic to the cheesemaking process. Therefore, there is no need for confusing and mandatory listing of these ingredients on the label. One of the comments noted that the Codex standard lists "necessary additions" such as starter, rennet, and salt, and "optional additions" such as smoke and calcium chloride. Another of the comments asserted that the listing of "milk" and "clotting enzymes" as optional ingredients is contrary to section 401 of the act (21 U.S.C. 341).

These comments apparently misunderstood FDA's purpose in providing for ingredients by class, rather than by specific name, in the proposed standard. As explained in the preamble to the proposal, FDA believes that it is technologically feasible to use many dairy ingredients other than fluid milk to produce cheese. Therefore, classes of dairy ingredients were defined and included under the designation "Optional Dairy Ingredients". Because manufacturers would have many options within the group of permitted dairy ingredients, FDA is requiring that the dairy ingredients used be declared in a label statement of ingredients by either of the options offered in paragraph (d)(2) of the proposed standard. This requirement is in keeping with FDA's policy, developed under section 401 of the act and stated in 21 CFR 101.6 to provide consumers with more complete information about the food they eat. FDA does not believe that this method of providing for forms of dairy ingredients other than fluid milk implies that dairy ingredients are not necessary to the manufacture of cheese, nor does FDA believe that listing the ingredients used in a food on the label of that food is confusing to consumers. The same holds true for optional clotting enzymes. It is not FDA's intention to adopt the Codex method of designating permitted ingredients because it is too restrictive and contrary to FDA's policy of permitting manufacturers the flexibility, within reason, to choose ingredients according to their availability in the marketplace and, thus, reduce consumer costs. Therefore, no change is made in the final regulation.

Samsoe Cheese

32. One comment requested that the maximum moisture level in the Codex standard for samsoe cheese be adopted. The maximum moisture level in the current U.S. standard (§ 133.185) is 41 percent; the maximum in the Codex standard is 44 percent. The comment pointed out that most of the samsoe cheese sold in the United States is produced in Denmark, a country that has accepted the Codex standard. Another comment from a national cheese producers' trade association stated that it is unaware of any of its members manufacturing samsoe cheese in this country.

FDA believes that raising the maximum moisture level by 3 percent would have a negative effect on the nutritional value of samsoe cheese. Because the milkfat minimum is to remain unchanged, a raise in the moisture maximum level would result in the milk solids content being proportionately reduced. Among the more important nutrients that would be reduced in quantity are protein and its associated minerals, calcium and phosphorus. Therefore, FDA is not raising the maximum moisture level to 44 percent, as requested.

Swiss and Emmentaler Cheese

33. Two comments were in favor of raising the minimum milkfat level in the proposed swiss and emmentaler cheese standard (§ 133.195) to conform to the minimum of 45 percent specified in the Codex standard. (The minimum milkfat requirement in the current U.S. standard is 43 percent. Both minima are calculated on a dry basis.) One other comment requested that the milkfat minimum level not be changed because the best quality swiss cheese has a milkfat content between 44 and 45.5 percent, on a dry basis, and that a milkfat content of 46 percent or more leads to poor eye formation and generally poor quality cheese. The latter comment did not want the minimum raised to 45 percent because, to assure that cheese meets this minimum, some would contain 46 percent or more milkfat and thus be of poorer quality.

FDA does not believe that the 43-percent minimum milkfat level for swiss cheese is in conflict with the Codex standard because it neither prevents manufacturers from producing swiss cheese with the higher milkfat content nor prevents other countries from exporting higher fat swiss and emmentaler cheese to the United States. Also, FDA has no technological data, nor were any supplied in the comments, to show that a 46-percent fat swiss cheese would be of poorer quality than a 43-percent or a 45-percent fat swiss cheese. Therefore, FDA is not raising the minimum milkfat level to conform to the Codex standard for swiss and emmentaler cheese.

Swiss Cheese for Manufacturing

34. One comment requested that the phrase "curing is not required" be added to the proposed standard for swiss cheese for manufacturing (§ 133.196) because the safety and esthetic reasons for curing the cheese are not applicable because it would undergo further processing.

FDA recognizes that curing of the cheese in lieu of pasteurization of the milk from which the cheese is made is not applicable to cheeses for manufacturing, but, in this case, curing is necessary to ensure that the flavor characteristics normally associated with swiss cheese are developed. Since swiss cheese for manufacturing must have the flavor of swiss cheese, and a curing period of at least 60 days is necessary for the characteristic flavor to develop, the curing requirement is being retained in the standard.

Monterey Cheese for Manufacturing

35. One comment requested that a standard for monterey cheese for manufacturing be established. The comment stated that monterey cheese is the only American-type cheese that does not have a manufacturing standard.

It is not appropriate for FDA to establish a standard of identity for monterey cheese for manufacturing at this point in the rulemaking proceedings. FDA invites any interested person who believes that a standard of identity for this food should be established to submit a petition presenting reasonable grounds in support of such action.

After considering the comments received, FDA concludes that it will promote honesty and fair dealing in the interest of consumers to revise the standards of identity for nine natural cheeses and appropriate cross-referenced standards.

The requirement for a regulatory flexibility analysis under the Regulatory Flexibility Act does not apply to this final rule because the proposed rule was issued prior to January 1, 1981, and is therefore exempt.

List of Subjects in 21 CFR Part 133

Cheese; Food standards, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 401, 701(e), 52 Stat. 1046, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 133 is amended as follows:

PART 133—CHEESES AND RELATED CHEESE PRODUCTS

1. By revising § 133.3 to read as follows:

§ 133.3 Definitions.

(a) "Milk" means the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows, which may be clarified and may be adjusted by separating part of the fat therefrom; concentrated milk, reconstituted milk, and dry whole milk. Water, in a sufficient quantity to reconstitute concentrated and dry forms, may be added.

(b) "Nonfat milk" means skim milk, concentrated skim milk, reconstituted skim milk, and nonfat dry milk. Water, in a sufficient quantity to reconstitute concentrated and dry forms, may be added.

(c) "Cream" means cream, reconstituted cream, dry cream, and plastic cream. Water, in a sufficient quantity to reconstitute concentrated and dry forms, may be added.

(d) "Pasteurized" when used to describe a dairy ingredient means that every particle of such ingredient shall have been heated in properly operated equipment to one of the temperatures specified in the table of this paragraph and held continuously at or above that temperature for the specified time (or other time/temperature relationship which has been demonstrated to be equivalent thereto in microbial destruction):

Temperature	Time
145° F[1]	90 min.
161° F[1]	15 s.
191° F	1 s.
204° F	0.05 s.
212° F	0.01 s.

[1] If the dairy ingredient has a fat content of 10 percent or more, the specified temperature shall be increased by 6° F.

(e) "Ultrapasteurized" when used to describe a dairy ingredient means that such ingredient shall have been thermally processed at or above 280° F for at least 2 seconds.

2. By adding new § 133.5, to read as follows:

§ 133.5 Methods of analysis.

Moisture, milkfat, and phosphatase levels in cheeses will be determined by the following methods of analysis from "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th ed., 1980, which is incorporated by reference (copies are available from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408):

(a) Moisture content—section 16.233 "Method I (52)—Official Final Action", under the heading "Moisture".

(b) Milk fat content—section 16.255 "Fat (60)—Official Final Action".

(c) Phenol equivalent value—section 16.275 "Reagents", section 16.276 "Sampling", and section 16.277 "Determination", under the heading "Residual Phosphatase (27) Official Final Action".

(d) Milkfat in solids (fat on a dry basis)—Subtract the percent of moisture found from 100; divide the remainder into the percent milkfat found. The quotient, multiplied by 100, shall be considered to be the percent of milkfat contained in the solids.

3. By revising § 133.106, to read as follows:

§ 133.106 Blue cheese.

(a) *Description.* (1) Blue cheese is the food prepared by the procedure set forth in paragraph (a)(3) of this section, or by any other procedure which produces a finished cheese having the same physical and chemical properties. It is characterized by the presence of bluish-green mold, *Penicillium roquefortii,* throughout the cheese. The minimum milkfat content is 50 percent by weight of the solids and the maximum moisture content is 46 percent by weight, as determined by the methods described in § 133.5. The dairy ingredients used may be pasteurized. Blue cheese is at least 60 days old.

(2) If pasteurized dairy ingredients are used, the phenol equivalent value of 0.25 gram of blue cheese is not more than 3 micrograms as determined by the method described in § 133.5.

(3) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be homogenized, bleached, warmed, and is subjected to the action of a lactic acid-producing bacterial culture. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. The mass is cut into smaller portions and allowed to stand for a time. The mixed curd and whey is placed in forms permitting further drainage. While the curd is being placed in forms, spores of the mold *Penicillium roquefortii* are added. The forms are turned several times during drainage. When sufficiently drained, the shaped curd is removed from the forms and salted with dry salt or brine. Perforations are then made in the shaped curd, and it is held at a temperature of approximately 50° F. at 90 to 95 percent relative humidity, until the characteristic mold growth has developed. During storage the surface of the cheese may be scraped to remove surface growth of undesirable microorganisms. Antimycotics may be applied to the surface of the whole cheese. One or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in § 133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Blue or green color in an amount to neutralize the natural yellow color of the curd.

(ii) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the dairy ingredients, used as a coagulation aid.

(iii) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(iv) Antimycotic agents, applied to the surface of slices or cuts in consumer-sized packages or to the surface of the bulk cheese during curing.

(v) Benzoyl peroxide or a mixture of benzoyl peroxide with potassium alum, calcium sulfate, and magnesium carbonate used to bleach the dairy ingredients. The weight of the benzoyl peroxide is not more than 0.002 percent of the weight of the milk being bleached, and the weight of the potassium alum, calcium sulfate, and magnesium carbonate, singly or combined, is not more than six times the weight of the benzoyl peroxide used. If milk is bleached in this manner, vitamin A is added to the curd in such quantity as to compensate for the vitamin A or its precursors destroyed in the bleaching process, and artificial coloring is not used.

(vi) Vegetable fats or oils, which may be hydrogenated, used as a coating for the rind.

(c) *Nomenclature.* The name of the food is "blue cheese."

(d) *Label declaration.* The common or usual name of each of the ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as "enzymes"; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms "milkfat and nonfat milk" or "nonfat milk and milkfat", as appropriate.

4. By revising §133.113, to read as follows:

§ 133.113 Cheddar cheese.

(a) *Description.* (1) Cheddar cheese is the food prepared by the procedure set forth in paragraph (a)(4) of this section, or by any other procedure which produces a finished cheese having the same physical and chemical properties. The minimum milkfat content is 31 percent by weight of the solids, and the maximum moisture content is 39 percent by weight, as determined by the methods described in § 133.5. If the dairy ingredients used are not pasteurized, the cheese is cured at a temperature of not less than 35° F for at least 60 days.

(2) If pasteurized dairy ingredients are used, the phenol equivalent value of 0.25 gram of cheddar cheese is not more than 3 micrograms as determined by the method described in § 133.5.

(3) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be warmed, treated with hydrogen peroxide/catalase, and is subjected to the action of a lactic acid-producing bacterial culture. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. The mass is so cut, stirred, and heated with continued stirring, as to promote and regulate the separation of whey and curd. The whey is drained off, and the curd is matted into a cohesive mass. The mass is cut into slabs, which are so piled and handled as to promote the drainage of whey and the development of acidity. The slabs are then cut into pieces, which may be rinsed by sprinkling or pouring water over them, with free and continuous drainage; but the duration of such rinsing is so limited that only the whey on the surface of such pieces is removed. The curd is salted, stirred, further drained, and pressed into forms. One or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in §133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Coloring.

(ii) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the dairy ingredients, used as a coagulation aid.

(iii) Enzymes of animal, plant, or microbial orgin, used in curing or flavor development.

(iv) Antimycotic agents, applied to the surface of slices or cuts in consumer-sized packages.

(v) Hydrogen peroxide, followed by a sufficient quantity of catalase preparation to eliminate the hydrogen peroxide. The weight of the hydrogen peroxide shall not exceed 0.05 percent of the weight of the milk and the weight of the catalase shall not exceed 20 parts per million of the weight of the milk treated.

(c) *Nomenclature.* The name of the food is "cheddar cheese".

(d) *Label declaration.* The common or usual name of each of the ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as "enzymes"; and

(2) The dairy ingredients may be declared, in descending order or predominance, by the use of the terms "milkfat and nonfat milk" or "nonfat milk and milkfat", as appropriate.

5. By revising § 133.114, to read as follows:

§ 133.114 Cheddar cheese for manufacturing.

Cheddar cheese for manufacturing conforms to the definition and standard of identity prescribed for cheddar cheese by § 133.113, except that the milk is not pasteurized, curing is not required, and the provisions of paragraph (b)(3)(iv) of that section do not apply.

6. By revising § 133.116, to read as follows:

§ 133.116 Low sodium cheddar cheese.

Low sodium cheddar cheese is the food prepared from the same ingredients and in the same manner prescribed in § 133.113 for cheddar cheese and complies with all the provisions of § 133.113, including the requirements for label statement of ingredients, except that:

(a) It contains not more than 96 milligrams of sodium per pound of finished food.

(b) The name of the food is "low sodium cheddar cheese". The letters in the words "low sodium" shall be of the same size and style of type as the letters in the words "cheddar cheese", wherever such words appear on the label.

(c) If a salt substitute is used, the label shall bear the statement "———— added as a salt substitute", the blank being filled in with the common name or names of the ingredient or ingredients used as a salt substitute.

(d) Low sodium cheddar cheese is subject to § 105.69 of this chapter.

7. By revising § 133.138, to read as follows:

§ 133.138 Edam cheese.

(a) *Description.* (1) Edam cheese is the food prepared by the procedure set forth in paragraph (a)(3) of this section or by any other procedure which produces a finished cheese having the same physical and chemical properties. The minimum milkfat content is 40 percent by weight of the solids, as determined by the methods described in § 133.5, and the maximum moisture content is 45 percent by weight. If the dairy ingredients used are not pasturized, the cheese is cured at a temperature of not less than than 35° for at least 60 days.

(2) If pasteurized dairy ingredients are used, the phenol equivalent value of 0.25 gram of edam cheese is not more than 3 micrograms, as determined by the method described in § 133.5.

(3) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be warmed and is subjected to the action of a lactic acid-producing bacterial culture. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. After coagulation the mass is cut into small cube-shaped pieces with sides approximately three-eighths-inch long. The mass is stirred and heated to about 90° F. and so handled by further stirring, heating, dilution with water or salt brine, and salting as to promote and regulate the separation of curd and whey. When the desired curd is obtained, it is transferred to forms permitting drainage of whey. During drainage the curd is pressed and turned. After drainage the curd is removed from the forms and is salted and cured. One or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedures.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in § 133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Coloring.

(ii) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the dairy ingredients, used as a coagulation aid.

(iii) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(iv) Antimycotic agents, applied to the surface of slices or cuts in consumer-sized packages.

(c) *Nomenclature.* The name of the food is "edam cheese."

(d) *Label declaration.* The common or usual name of each of the ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as "enzymes"; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms "milkfat and nonfat milk" or "nonfat milk and milkfat," as appropriate.

8. By revising § 133.142, to read as follows:

§ 133.142 Gouda cheese.

Gouda cheese conforms to the definition and standard of identity and complies with the requirements for label declaration of ingredients prescribed for edam cheese by § 133.138, except that the minimum milkfat content is 46 percent by weight of the solids, as determined by the methods described in § 133.5 and the maximum moisture content is 45 percent by weight.

9. By revising § 133.149, to read as follows:

§ 133.149 Gruyere cheese.

(a) *Description.* (1) Gruyere cheese is the food prepared by the procedure set forth in paragraph (a)(3) of this section or by any other procedure which produces a finished cheese having the same physical and chemical properties. It contains small holes or eyes. It has a mild flavor, due in part to the growth of surface-curing agents. The minimum milkfat content is 45 percent by weight of the solids, as determined by methods described in § 133.5. The dairy ingredients used may be pasteurized. The cheese is at least 90 days old.

(2) If pasteurized dairy ingredients are used, the phenol equivalent value of 0.25 gram of gruyere cheese is not more than 3 micrograms as determined by the method described in § 133.5.

(3) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be warmed and is subjected to the action of lactic acid-producing and propionic acid-producing bacterial cultures. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. The mass is cut into particles similar in size to wheat kernels. For about 30 minutes the particles are alternately stirred and allowed to settle. The temperature is raised to about 126° F. Stirring is continued until the curd becomes firm. The curd is transferred to hoops or forms, and pressed until the desired shape and firmness are obtained. The cheese is surface-salted while held at a temperature of 48° to 54° F for a few days. It is soaked for 1 day in a saturated salt solution. It is then held for 3 weeks in a salting cellar and wiped every 2 days with brine cloth to insure growth of biological curing agents on the rind. It is then removed to a heating room and held at progressively higher temperatures, finally reaching 65° F with a relative humidity of 85 to 90 percent, for several weeks, during which time small holes, or so-called eyes, form. The cheese is then stored at a lower temperature for further curing. One or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in § 133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Calcium chloride in an amount not more than 0.002 percent (calculated as anhydrous calcium chloride) of the weight of the dairy ingredients, used as a coagulation aid.

(ii) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(iii) Antimycotic agents, applied to the surface of slices or cuts in consumer-sized packages.

(c) *Nomenclature.* The name of the food is "gruyere cheese".

(d) *Label declaration.* The common or usual name of each of the ingredients used in the food shall be declared on the label as required by the applicable sections of part 101 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as "enzymes"; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms "milkfat and nonfat milk" or "nonfat milk and milkfat", as appropriate.

10. By revising § 133.152, to read as follows:

§ 133.152 Limburger cheese.

(a) *Description.* (1) Limburger cheese is the food prepared by one of the procedures set forth in paragraph (a)(3) of this section, or by any other procedure which produces a finished cheese having the same physical and chemical properties. The minimum milkfat content is 50 percent by weight of the solids and the maximum moisture content is 50 percent by weight, as determined by the methods described in § 133.5. If the dairy ingredients used are not pasteurized, the cheese is cured at a temperature of 35° F for at least 60 days.

(2) If pasteurized dairy ingredients are used, the phenol equivalent value of 0.25 gram of limburger cheese is not more than 4 micrograms as determined by the method described in § 133.5.

(3) One of the following procedures may be followed for producing limburger cheese:

(i) One or more of the dairy ingredients, unpasteurized, specified in paragraph (b)(1) of this section is warmed to about 92° F and subjected to the action of a lactic acid-producing bacterial culture. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. The mass is cut into cubes with sides approximately one-half inch long. After a few minutes the mass is stirred and heated, gradually raising the temperature to 96° to 98° F. The curd is then allowed to settle, most of the whey is drained off, and the remaining curd and whey dipped into molds. During drainage the curd may be pressed. It is turned at regular intervals. After drainage the curd is cut into pieces of desired size and dry-salted at intervals for 24 to 48 hours. The cheese is then cured with frequent applications of a weak brine solution to the surface, until the proper growth of surface-curing organisms is obtained. It is then wrapped and held in storage for development of as much additional flavor as is desired. One or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(ii) One or more of the dairy ingredients specified in paragraph (b)(1) of this section is pasteurized, brought to a temperature of 89° to 90° F. after pasteurization, and is subjected to the

action of a lactic acid-producing bacterial culture. The procedure is then the same as in paragraph (a)(3)(i) of this section, except that heating is to 94° F. After most of the whey is drained off, salt brine at a temperature of 66° to 70° F is added, so that the pH of the curd is about 4.8. The mixed curd, whey, and brine is dipped into molds, and the remaining procedure specified in paragraph (a)(3)(i) of this section is followed.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in § 133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Coloring.

(ii) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) by weight of the dairy ingredients, used as a coagulation aid.

(iii) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(c) *Nomenclature.* The name of the food is "limburger cheese".

(d) *Label declaration.* The common or usual name of each of the ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as "enzymes"; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms "milkfat and nonfat milk" or "nonfat milk and milkfat", as appropriate.

11. By revising § 133.181, to read as follows:

§ 133.181 Provolone cheese.

(a) *Description.* (1) Provolone, a pasta filata or stretched curd-type cheese, is the food prepared by the procedure set forth in paragraph (a)(3) of this section, or by any other method which produces a finished cheese having the same physical and chemical properties. It has a stringy texture. The minimum milkfat content is 45 percent by weight of the solids, as determined by the methods described in § 133.5 and the maximum moisture content is 45 percent by weight. If the dairy ingredients used are not pasteurized, the cheese is cured at a temperature of not less than 35° F for at least 60 days.

(2) If pasteurized dairy ingredients are used, the phenol equivalent value of 0.25 gram of provolone cheese is not more than 3 micrograms as determined by the method described in § 133.5.

(3) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be bleached, warmed, and is subjected to the action of a lactic acid-producing bacterial culture. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. The mass is cut, stirred, and heated so as to promote and regulate the separation of whey from the curd. The whey is drained off, and the curd is matted and cut, immersed in hot water, and kneaded and stretched until it is smooth and free from lumps. Antimycotics may be added to the curd during the kneading and stretching process. Then it is cut and molded. During the molding the curd is kept sufficiently warm to cause proper sealing of the surface. The molded curd is then firmed by immersion in cold water, salted in brine, and dried. It is given some additional curing. Provolone cheese may be smoked, and one or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in § 133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Blue or green color in an amount to neutralize the natural yellow color of the curd.

(ii) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) by weight of the dairy ingredients, used as a coagulation aid.

(iii) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(iv) Antimycotic agents, applied to the surface of slices or cuts in consumer-sized packages or added to the curd during the kneading and stretching process.

(v) Benzoyl peroxide or a mixture of benzoyl peroxide with potassium alum, calcium sulfate, and magnesium carbonate used to bleach the dairy ingredients. The weight of the benzoyl peroxide is not more than 0.002 percent of the weight of the milk being bleached, and the weight of the potassium alum, calcium sulfate, and magnesium carbonate, singly or combined, is not more than six times the weight of the benzoyl peroxide used. If milk is bleached in this manner, vitamin A is added to the curd in such quantity as to compensate for the vitamin A or its precursors destroyed in the bleaching process, and artificial coloring is not used.

(c) *Nomenclature.* (1) The name of the food is "provolone cheese". The name of the food may include the common name of the shape of the cheese, such as "salami provolone".

(2) One of the following terms, in letters not less than one-half the height of the letters used in the name of the food, shall accompany the name of the food wherever it appears on the principal display panel or panels:

(i) "Smoked" if the food has been smoked.

(ii) "Not smoked" if the food has not been smoked.

(d) *Label declaration.* The common or usual name of each of the ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as "enzymes"; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms "milkfat and nonfat milk" or "nonfat milk and milkfat", as appropriate.

12. By revising § 133.185, to read as follows:

§ 133.185 Samsoe cheese.

(a) *Description.* (1) Samsoe cheese is the food prepared by the procedure set forth in paragraph (a)(3) of this section or by any other procedure which produces a finished cheese having the same physical and chemical properties. It has a small amount of eye formation of approximately uniform size of about five-sixteenths inch (8 millimeters). The minimum milkfat content is 45 percent by weight of the solids and the maximum moisture content is 41 percent by weight, as determined by the methods described in § 133.5. The dairy ingredients used may be pasteurized. Samsoe is cured at not less than 35°F for at least 60 days.

(2) If pasteurized dairy ingredients are used, the phenol equivalent value of 0.25 gram of samsoe cheese is not more than 3 micrograms as determined by the method described in § 133.5.

(3) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be warmed and is subjected to the action of a lactic acid-producing bacterial culture. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added

to set the dairy ingredients to a semisolid mass. After coagulation the mass is cut into small cube-shaped pieces with sides approximately three-eighths inch (1 centimeter). The mass is stirred and heated to about 102° F, and so handled by further stirring, heating, dilution with water, and salting as to promote and regulate the separation of curd and whey. When the desired curd is obtained, it is transferred to forms permitting drainage of whey. During drainage, the curd is pressed. After drainage, the curd is removed from the forms and is further salted by immersing in a concentrated salt solution for about 3 days. The curd is then cured at a temperature of from 60° to 70° F for 3 to 5 weeks to obtain the desired eye formation. Further curing is conducted at a lower temperature. One or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in § 133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Coloring.

(ii) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) by weight of the dairy ingredients, used as a coagulation aid.

(iii) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(iv) Antimycotic agents, applied to the surface of slices or cuts in consumer-sized packages.

(c) *Nomenclature.* The name of the food is "samsoe cheese".

(d) *Label declaration.* The common or usual name of each of the ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as "enzymes"; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms "milkfat and nonfat milk" or "nonfat milk and milkfat", as appropriate.

13. By revising § 133.195, to read as follows:

§ 133.195 Swiss and emmentaler cheese.

(a) *Description.* (1) Swiss cheese, emmentaler cheese, is the food prepared by the procedure set forth in paragraph (a)(3) of this section, or by any other procedure which produces a finished cheese having the same physical and chemical properties. It has holes or eyes developed throughout the cheese. The minimum milkfat content is 43 percent by weight of the solids and the maximum moisture content is 41 percent by weight, as determined by the methods described in § 133.5. The dairy ingredients used may be pasteurized. Swiss cheese is at least 60 days old.

(2) If pasteurized dairy ingredients are used, the phenol equivalent value of 0.25 gram of swiss cheese is not more than 3 micrograms as determined by the method described in § 133.5.

(3) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be bleached, warmed, or treated with hydrogen peroxide/catalase, and is subjected to the action of lactic acid-producing and propionic acid-producing bacterial cultures. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. The mass is cut into particles similar in size to wheat kernels. For about 30 minutes the particles are alternately stirred and allowed to settle. The temperature is raised to about 126° F. Stirring is continued until the curd becomes firm. The acidity of the whey at this point, calculated as lactic acid, does not exceed 0.13 percent. The curd is transferred to hoops or forms and pressed until the desired shape and firmness are obtained. The cheese is then salted by immersing it in a saturated salt solution for about 3 days. It is then held at a temperature of about 50° to 60° F. for a period of 5 to 10 days, after which it is held at a temperature of about 75° F. until it is approximately 30 days old, or until the so-called eyes form. Salt, or a solution of salt in water, is added to the surface of the cheese at some time during the curing process. The cheese is then stored at a lower temperature for further curing. One or more of the optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in § 133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Coloring.

(ii) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) by weight of the dairy ingredients, used as a coagulation aid.

(iii) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(iv) Antimycotic agents, applied to the surface of slices or cuts in consumer-sized packages.

(v) Benzoyl peroxide or a mixture of benzoyl peroxide with potassium alum, calcium sulfate, and magnesium carbonate used to bleach the dairy ingredients. The weight of the benzoyl peroxide is not more than 0.002 percent of the weight of the milk being bleached, and the weight of the potassium alum, calcium sulfate, and magnesium carbonate, singly or combined, is not more than six times the weight of the benzoyl peroxide used. If milk is bleached in this manner, vitamin A is added to the curd in such quantity as to compensate for the vitamin A or its precursors destroyed in the bleaching process, and artificial coloring is not used.

(vi) Hydrogen peroxide, followed by a sufficient quantity of catalase preparation to eliminate the hydrogen peroxide. The weight of the hydrogen peroxide shall not exceed 0.05 percent of the weight of the milk and the weight of the catalase shall not exceed 20 parts per million of the weight of the milk treated.

(c) *Nomenclature.* The name of the food is "swiss cheese", or alternatively, "emmentaler cheese".

(d) *Label declaration.* The common or usual name of each of the ingredients used in the food shall be declared on the label as required by the applicable sections of part 101 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as "enzymes"; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms "milkfat and nonfat milk" or "nonfat milk and milkfat", as appropriate.

14. By revising § 133.196, to read as follows:

§ 133.196 Swiss cheese for manufacturing.

Swiss cheese for manufacturing conforms to the definition and standard of identity prescribed for swiss cheese by § 133.195, except that the holes, or eyes, have not developed throughout the entire cheese, and the provisions of paragraph (b)(3)(iv) of that section do not apply; however, the labeling requirements of paragraph (d) of that section do apply.

Any person who will be adversely affected by the foregoing regulation may at any time on or before February 22, 1983, submit to the Dockets Management Branch (address above), written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. Except as to any provisions that may be stayed by the filing of proper objections, compliance with this final regulation, including any required labeling changes, may begin March 22, 1983, and all affected products initially introduced or initially delivered for introduction into interstate commerce on or after July 1, 1985 shall fully comply. Notice of the filing of objections or lack thereof will be published in the **Federal Register.**

(Secs. 401, 701(e), 52 Stat. 1046, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e)))

Dated: January 17, 1983.

William F. Randolph,

Acting Assistant Commissioner for Regulatory Affairs.

[FR Doc. 83-1842 Filed 1-20-83; 8:45 am]

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21 CFR Part 145

[Docket No. 79N-0231]

Canned Berries; Standard of Identity; Confirmation of Effective Date and Further Amendment

AGENCY: Food and Drug Administration.

ACTION: Final rule; confirmation of effective date and further amendment.

SUMMARY: The Food and Drug Administration (FDA) confirms the effective date for compliance with the provisions of the amended standard of identity for canned berries and further amends the standard to provide for the use of safe and suitable nutritive carbohydrate sweeteners as optional ingredients.

DATES: Compliance with the provision being revised herein may begin March 22, 1983. Effective July 1, 1985, for all affected products initially introduced or initially delivered for introduction into interstate commerce on or after this date.

Objections to the provision being revised herein by February 22, 1983.

Compliance with the provisions amended in the **Federal Register** of January 9, 1981 (46 FR 2339) may have begun February 10 1981, and all affected products initially introduced or initially delivered for introduction into interstate commerce on or after July 1, 1983, shall fully comply.

ADDRESS: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: F. Leo Kauffman, Bureau of Foods (HFF-214), Food and Drug Administration, 200 C St. SW., Washington, DC 20204; 202-245-1164.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 9, 1981 (46 FR 2339), FDA issued a final rule amending the U.S. standard of identity for canned berries (21 CFR 145.120(a)) in consideration of the identity provisions of the Recommended International Standard for Canned Raspberries and the Recommended International Standard for Canned Strawberries developed by the Codex Alimentarius Commission of the Food and Agriculture Organization of the United Nations and of the World Health Organization (FAO/WHO). The final rule was based on a proposal published in the **Federal Register** of September 25, 1979 (44 FR 55191). Any person who would be adversely affected by the final rule could have, at any time on or before February 9, 1981, filed written objections to the final regulation and requested a hearing on the specific provisions to which there were objections.

The Whey Products Institute (WPI) objected to and requested a hearing on the limitation of the use of optional sweeteners to those named in the final rule (21 CFR 145.120 (a) (4) (iv)) because lactose was not included. WPI said that failure to allow the use of any safe and suitable nutritive carbohydrate sweetener, such as lactose, as an optional ingredient in canned berries is inconsistent with the generic permission given to the use of optional flavors, organic acids, and fruit juices as found in this rule. It pointed out that lactose, obtained from whey, is considered a safe and suitable optional nutritive carbohydrate sweetener and referred to the standard of identity for lactose in 21 CFR 168.122. WPI also asserted that appropriate sweeteners cannot be excluded solely because FDA is not aware of their use in canned berries.

The September 25, 1979, proposal to amend the standard of identity for canned berries provided for the use of safe and suitable nutritive carbohydrate sweeteners. Subsequent to the proposal, FDA, the United States Department of Agriculture (USDA), and the staff of the Federal Trade Commission's Bureau of Consumer Protection (FTC) announced in the **Federal Register** of December 21, 1979 (44 FR 75990) their tentative positions on a variety of food-related issues. A revision in FDA's policy with regard to safe and suitable ingredients in standardized foods was considered. The January 9, 1981, final rule reflected FDA's December 21, 1979, tentative policy by specifically listing those safe and suitable nutritive carbohydrate sweeteners allowed in canned berries.

Upon review and evaluation of the comments received in response to the December 21, 1979, tentative position, however, FDA has determined that, at this time, it would be in the best interest of the consumers and the regulated industry to retain its established policy for use of safe and suitable optional ingredients in standardized foods. Elsewhere in this issue of the **Federal Register** FDA is announcing this decision. This decision has the effect of acceeding to WPI's objection that all safe and suitable nutritive carbohydrate sweeteners should be optional ingredients.

Therefore, FDA is removing § 145.120(a)(4)(iv) that would have listed permitted nutritive carbohydrate sweeteners as optional ingredients and is revising § 145.120(a)(3)(i) to allow the use of safe and suitable nutritive carbohydrate sweeteners in canned berries as proposed.

List of Subjects in 21 CFR Part 145

Canned fruit, Food standards, Fruits.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 401, 701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), notice is given that the